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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,883	12/15/2003	Diane Lipscombe	B0877.70026US00	6781

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EXAMINER	
STANDLEY, STEVEN H	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,883	LIPSCOMBE ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-18,24 and 26-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-4, 7-18, 24, 26-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a cell that expresses recombinant N-type calcium channel subunit splice variant, classified in class 435, subclass 69.1.

II. Claims 7-11 drawn to an isolated nociceptive neuron expressing the Cav2.2e [37a] splice variant classified in 435, subclass 325.

III. Claims 12-15, and 24 drawn to method of identifying lead compounds by measuring calcium influx that are useful in the treatment of disease associated with Cav2.2e[37a] subunit-containing N-type calcium channels by, classified in class 435, subclass 7.21.

IV. Claims 16-17 and 24 as drawn to a method for identifying compounds that bind Cav2.2e[37a] subunit-containing N-type calcium channels, classified in class 436, subclass 501.

V. Claims 18 and 24 as drawn to a method of identifying compounds that bind to Cav2.2e[37a] polypeptide, but not to Cav2.2e[37b] polypeptide, wherein the compound is an antibody or fragment thereof, classified in class 435, subclass 7.1.

VI. Claims 26-30, as drawn to an RNA molecule specific for Cav2.2e [37a], classified in class 536, subclass 24.5.

VII. Claims 31-32, as drawn to a method for inhibiting calcium influx in neurons through Cav2.2e[37a] channels using an antibody, an antisense oligonucleotides, or an siRNA classified in class 536, subclass 24.5.

VIII. Claims 33-36, as drawn to a method of treating a subject afflicted by pain using an antibody, an antisense nucleic acid, or an siRNA classified in class 536, subclass 24.5.

2. The inventions are distinct, each from the other for the following reasons: Although there are no provisions under the section "Relation Inventions" in MPEP § 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products appear to constitute patently distinct inventions for the following reasons:

Inventions I, II are directed to products that are functionally unrelated, involving cells expressing a recombinant Cav2.2e[37a], and isolated neurons expressing Cav2.2e[37a]. For instance, Group I is an isolated cell expressing a recombinant Cav2.2e[37a] protein, and can be made prepared by transfecting a plasmid DNA appropriately equipped to express the Cav2.2e[37a] cDNA. Group II is an isolated, nociceptive neuron expressing Cav2.2e[37a], and can be prepared from appropriate tissue using standard isolation techniques. Therefore these are unrelated products that do not have the same function or method of preparation and would constitute and undue search burden.

Inventions I-II are each related to each of the inventions III-V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case inventions III-V are distinct methods directed at using inventions I and II, but are capable of being used with materially different products. For instance, the methods of Group III-V can be used with Cav2.2[37a] channel integrated into the membranes of liposomes or other artificial membranes, as pointed out in the method claims themselves. Thus, because the inventions are distinct, the searches would not be coextensive and would constitute and undue search burden.

Inventions I-II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case an isolated cell expressing recombinant N-type Calcium channel subunit splice variant, Cav2.2[37a], can be used for a method of identifying new compounds that modulate Cav2.2[37a] as apposed to "a method of inhibiting" with an antibody, with antisense oligos, or siRNAs. The isolated neuron expressing Cav2.2[37a] of invention II can be used in a similar manner as described for invention I. Thus, because the inventions are distinct, the searches would not be coextensive and would constitute an undue search burden.

Inventions I-II each are unrelated to invention VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions cannot be used together since invention IX is a method of treating a subject afflicted with pain by administration of a product (an antibody, a nucleic acid, or an siRNA) unrelated to inventions I and II, which are to cells which cannot reasonably be used to treat pain in a subject. Thus, because the inventions are unrelated, the searches would not be coextensive and would constitute an undue search burden.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Groups III-V each are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group III is drawn to a method of identifying lead compounds by measuring the voltage-regulated calcium influx through Cav2.2[37a], which has different steps and requires entirely different measurements than groups IV- V., which are methods of identifying compounds which simply ***bind*** to Cav2.2[37a] . Furthermore, Group III is classified differently than inventions IV-V and would constitute an undue search burden. Groups IV-V are distinct methods of identifying compounds that each use materially different products and therefore would constitute an undue search burden. Group IV is a method of identifying compounds that bind the Cav2.2e(37a) subnit, whereas

group V is a method of identifying compounds that bind [37a] and ***not*** [37b]. Groups IV-V clearly also search for products that are materially different from each other. Therefore a search and examination of the methods of group III-V would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different in some cases and the subject matter divergent.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: group VII-VIII are methods of inhibiting calcium influx by administration of an antibody, an antisense oligonucleotide, or siRNA and a method of treating a patient afflicted with pain by administering the same. The two methods have different goals and are administered to different populations. Therefore a search and examination of the methods of group VII-VIII would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different in some cases and the subject matter divergent.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: group VII-VIII are separate and distinct from the methods of groups III-V, which are methods of

identifying compounds by contacting with a candidate molecule and measuring calcium influx, or binding, or specific binding to the calcium channel subunit and splice variant. Groups VII-VIII are method of inhibiting calcium influx or treating a patient using a compound or antibody, or siRNA known to inhibit the calcium channel subunit. The goals are entirely different, the methods use different steps and different compounds. Therefore a search and examination of the methods of group III-V with groups VII-VIII would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different in some cases and the subject matter divergent.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Group VI is to a double-stranded RNA molecule which is different than the cells recited in the claims of groups I-II. The groups are distinct products that can be used independently of one another. Therefore a search and examination of the methods of group VI with groups I-II would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different in some cases and the subject matter divergent.

Inventions VI, III-V and VII-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods of identifying can be used to identify other molecules besides a double-stranded RNA molecule. Further, the method of inhibition calcium influx and method of treating of groups VII-VIII can be accomplished with an antibody to the calcium channel rather than RNA.

Election of Species

Should Applicant elect the invention of group I, a further election of species is required. The application contains claims directed to the following patentably distinct species: human, mouse, and rat Cav2.2[37a] splice variant. The species are independent or distinct because they have different sequences that are patentably distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Cav2.2[37a] is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant elect the invention of groups VII or VIII, a further election of species is required. The application contains claims directed to the following patentably distinct species: an antibody, an antisense nucleic acid, an siRNA. The species are independent or distinct because they have different sequences that are patentably distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, a Cav2.2[37a] inhibitor is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR

1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

In re Ochiai

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
9/27/06

DAVID S. ROMEO
PRIMARY EXAMINER